IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	MDL No. 2545 Master Docket Case No. 1:14-cv-01748 Honorable Matthew F. Kennelly
This document applies to: *Holtsclaw v. Endo Pharmaceuticals, Inc., et al.* Case No. 1:15-cv-3941 *Owens v. Auxilium Pharmaceuticals, Inc.*, Case No. 1:14-cv-5180	

PLAINTIFFS' STEERING COMMITTEE'S MEMORANDUM OF LAW IN OPPOSITION TO MOTION OF AUXILIUM DEFENDANTS TO EXCLUDE TESTIMONY UNDER FEDERAL RULES OF EVIDENCE 702 AND 403

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INTRODUCTION

Defendants Endo Pharmaceuticals, Inc., Auxilium Pharmaceuticals, LLC, and GlaxoSmithKline LLC (together, "Auxilium" or "Defendants") seek to exclude portions of the testimony of three of Plaintiffs' regulatory and marketing experts, Dr. Peggy Pence, Dr. Steven Woloshin, and Dr. David Handelsman, that Defendants knowingly marketed Testim, a testosterone-replacement therapy ("TRT") product, to middle-aged and older men to use, and their doctors to prescribe, for an off-label constellation of symptoms and an invented condition, "Low T." Defendants also seek to exclude the opinions of Plaintiffs' causation experts that Testim caused the heart attack suffered by Plaintiff Steven Holtsclaw and the deep-vein thrombosis ("DVT") suffered by Plaintiff Isaac Owens.

The motion should be denied in its entirety. This Court has already found, in the context of similar motions filed by the AbbVie Defendants, that similar opinions of Drs. Pence, Woloshin, and Handelsman are reliable and, with certain limitations, admissible under Fed. R. Evid. 702. *See* CMO 48. To the extent that Auxilium makes new arguments not previously considered by the Court with respect to these experts, those arguments are lacking in merit and should be rejected.

Like all TRT products, Testim is approved only for the treatment of classical hypogonadism, a rare pathological condition. Testim has never been shown to be effective in treating the non-specific age-related symptoms, such as reduced energy, lower libido, and changes in memory or mood, for which it was marketed, even when those symptoms are accompanied by serum levels of testosterone below the "normal" range for healthy young men. Indeed, reduced levels of testosterone in the blood often accompany other medical conditions common in aging men, such as obesity, Type 2 diabetes, metabolic syndrome, and atherosclerotic cardiovascular disease. These conditions are not the result of reduced testosterone levels, but often themselves cause reductions in testosterone serum levels. Aging men with these conditions are already at increased risk for major cardiovascular events. Because Testim can further increase that risk, these

are precisely the men for whom Testim is most dangerous -- but they were the target of Defendants' marketing efforts.

Furthermore, Defendants knew that Testim had never been shown to be safe and effective for use in treating age-related reduced levels of testosterone or the general symptoms of aging. Plaintiffs' evidence shows repeated attempts -- starting with the original New Drug Application ("NDA") -- by Defendants to convince the FDA to add an indication to the approved label for so-called "age-related hypogonadism." But at every juncture, the FDA refused to expand the label, and continually reminded Defendants that its products were not approved for the treatment of age-related hypogonadism, late-onset hypogonadism, or "andropause," which were not officially recognized diagnoses. Defendants nonetheless focused their marketing on precisely the symptoms for which the FDA refused to approve Testim, and Defendants failed to inform doctors or patients that Testim had never been shown to be safe or effective for use in the aging patients who were rapidly becoming the primary consumers of the product.

Defendants both failed to warn of the dangers of Testim and also exaggerated the benefits of the drug. They marketed it as effective to treat symptoms for which it has never been shown to be effective and failed to inform patients and physicians that Testim had never been shown to be safe or effective when used for the conditions and symptoms for which they aggressively marketed it. In this way, Defendants distorted both sides of the risk-benefit calculation physicians make when deciding to prescribe a drug. Risks that a doctor or patient would be willing to take to obtain relief from bothersome symptoms cannot be justified when there is no evidence to show that the drugs is able to provide such relief and when its safety profile in the context of those symptoms is unknown.

The testimony of Drs. Pence, Woloshin, and Handelsman will assist the jury in understating the lack of safety and efficacy information for Testim in aging men; the significance of the FDA's

refusal to approve Testim for so-called "age-related hypogonadism" or the group of symptoms for which Auxilium marketed it; Defendants' off-label marketing strategies and their focus on marketing Testim specifically for conditions for which it had never been approved; and the health risks Testim may have posed, both generally and specifically to men in Testim's targeted demographic. As explained below, this testimony is admissible and relevant and should not be excluded.

As for Plaintiffs' specific causation experts, the three who offer specific causation opinions, Dr. Hossein Ardehali with respect to Plaintiff Holtsclaw, and Dr. Jihad Abbas and Dr. Ardel Cagata with respect to Plaintiff Owens all used a differential etiology to arrive at their conclusion. As described below, their opinions are well-supported and should not be excluded. The fourth causation expert, Dr. Martin Ozor, is Plaintiff Owens's family physician. He offers an opinion about the connection between exogenous testosterone and clotting. As discussed below, this Court should deny Auxilium's motion to exclude the opinions of these experts and allow Plaintiffs Holtsclaw and Owens to offer the opinions of their respective causation experts.

PLAINTIFFS' EXERTS AND THEIR OPINIONS

Plaintiffs provided Defendants two expert reports from Dr. Hossein Ardehali (one on general causation and one on specific causation in Plaintiff Holtsclaw's case). They also provided expert reports from Dr. B. Burt Gerstman; Dr. Martin Wells; Dr. David J. Handelsman; Dr. Peggy Pence; Dr. Steven Woloshin; and Dr. Jihad Abbas.[1] In addition, based on testimony elicited at deposition, Plaintiffs designated two of Plaintiff Owens's treating physicians, Dr. Ardel Cagata and Dr. Martin Ozor, as non-retained, non-reporting experts and provided disclosure concerning their expected testimony pursuant to Fed. R. Civ. P. 26(a)(2)(c). Defendants have not challenged

[1] Plaintiffs also provided an expert report from Dr. Perry Halushka but later learned that, because of health issues, Dr. Halushka would not be able to provide expert testimony in these cases and so informed the Defendants.

the general causation opinion of Dr. Ardehali, nor the opinions of Dr. Gerstman or Dr. Wells; with respect to some of the remaining experts, Defendants challenge only limited portions of their proposed testimony. Accordingly, Plaintiffs will address only the opinions Defendants have challenged – certain portions of the opinions of Dr. Pence, Dr. Handelsman, and Dr. Woloshin; the specific-causation opinions of Dr. Ardehali and Dr. Abbas; and the opinions of Dr. Cagata and Dr. Ozor.

Peggy Pence, Ph.D., RAC, FRAPS

Dr. Pence has a B.S. in microbiology from Louisiana Polytechnic University and a Ph.D. in Toxicology, with a Pharmacology minor, from Indiana University. Pence Rep. Exhibit 1 at 1. She performed her doctoral research predominantly at the Eli Lilly Laboratory for Clinical Research. *Id.* She holds the U.S. Regulatory Certification (RAC). *Id.* The RAC certification is the only certification specifically for regulatory professionals in the healthcare sector. *Id.* She also has the peer-reviewed qualifications of a Fellow of the Regulatory Affairs Professionals Society based on professional experience, credentials, and training. *Id.* She has achieved the highest level of experience within her profession, Level IV, as outlined in the Regulatory Affairs Professional Development Framework. *Id.* Dr. Pence's extensive experience is provided in her report and was set forth in details in Plaintiffs' opposition to AbbVie's similar motion to exclude her testimony. Defendants do not, in any event, challenge her qualifications.

Dr. Pence offers six opinions: (1) Defendants promoted Testim for off-label uses; (2) Defendants failed to conduct adequate studies to demonstrate the safety and effectiveness of Testim for the off-label uses for which they promoted it; (3) Defendants marketed and sold a misbranded product in violation of federal regulations and the industry standard of care; (4) Defendants knew that Testim was being prescribed off-label and knew of serious concerns about a potential increase in cardiovascular events with testosterone use in high-risk patients; (5) Auxilium failed to manage post-marketing risk and failed to provide an adequate label; and

(6) patients and physicians were not provided sufficient information to make reasoned and informed decisions about Testim prescription and use.

Steven Woloshin, M.D., M.S.

Dr. Woloshin is a Professor of Medicine and Community and Family Medicine at the Dartmouth Geisel School of Medicine in Hanover, New Hampshire, and Co-Director of the Center for Medicine and the Media at the Dartmouth Institute for Health Policy and Clinical Practices. *See* Report of Steven Woloshin, MD, MS ("Woloshin Rep.") at 1-3, attached hereto as Exhibit 2. As is the case with Dr. Pence, Dr. Woloshin's credentials and experience can be found in his report and were set forth in Plaintiffs' opposition to AbbVie's motion to exclude his testimony.

Dr. Woloshin's opinions include an explanation of the concept of "disease mongering" or "selling sickness," a process by which pharmaceutical companies or others with similar interests may convince people that they have a disease that needs to be treated, often in order to sell that treatment.[2] As Dr. Woloshin explains, "[t]ypically, the proposed treatment is directed towards a disease with vague boundaries and ambiguous or nonspecific symptoms. These symptoms generally span a broad spectrum of severity. . . ." Report, Ex. 2, at 9. Dr. Woloshin further opines – as he did in an invited, published article in JAMA INTERNAL MEDICINE in 2013 – that "Low T" is a "classic example of disease mongering." *Id*. at 10. Dr. Woloshin also offers the opinion that the "Low T" promotional campaign—which includes the campaign the Auxilium Defendants engaged in—used strategies typical of disease mongering or selling sickness, including setting a low bar for diagnosis of the "disease"; raising the stakes of not being diagnosed to drive people to seek testing and treatment; and suggesting dire health consequences if the "disease" is left untreated. *Id*. at 10-11. Dr. Woloshin explains how the marketing and promotional plans and materials for Testim show that Defendants took advantage of the disease awareness marketing

[2] As discussed below, *see* Point I-B, Plaintiffs recognize that this Court has already held that Dr. Woloshin may not use the term "disease-mongering" in his testimony.

campaigns by the sellers of AndroGel. He further opines that Auxilium leveraged a set of non-specific symptoms and a biochemical test into a "disease" that the company equated with hypogonadism. Auxilium further leveraged the known decline in serum testosterone levels associated with certain other conditions and implied that the decline in testosterone was responsible for those conditions. The company also implicitly—and at times explicitly—states that reversal of the decline in serum testosterone levels would positively affect patients with those conditions.

Dr. Woloshin offers the opinion that these representations were false and misleading. He also opines that Auxilium's promotion of Testim was a "mass uncontrolled experiment conducted without the usual safeguards for drug testing." Ex. 1 at 17. He further opines that Auxilium did not warn or otherwise advise the medical community and the general public of the experimental nature of off-label testosterone use. Finally, Dr. Woloshin opines that Auxilium marketed Testim for off-label use while knowing that it lacked safety data that would support the use of Testim in the high-risk populations to which it marketed the product.

David Handelsman, MB, BS, Ph.D

Dr. Handelsman is an Australian physician and Professor of Reproductive Endocrinology and Andrology at the University of Sydney. He earned his MB BS (Bachelor of Medicine, Bachelor of Surgery), the Australian medical degree, at the University of Melbourne and his Ph.D. in Medicine at the University of Sydney. Dr. Handelsman is a world-renowned expert in Endocrinology and Andrology, having published over 390 peer-reviewed articles, 455 scientific meeting abstracts, and contributed to over 140 books, chapters, reviews and editorials, including three chapters in the treatise, DeGroot's ENDOCRINOLOGY. He is a Fellow of the Royal Australasian College of Physicians (FRACP) and a Fellow of the Australian Academy of Health and Medical Sciences (FAHMS). His qualifications and experience are set forth in his report and discussed in Plaintiffs' opposition to AbbVie's motion to exclude his testimony.

Dr. Handelsman explains why male aging is not an indication for testosterone replacement therapy. He provides important context, explaining how testosterone works as well as the history of testosterone pharmacology and pharmaceutical products. He explains the nature of androgen deficiency and the accepted uses for testosterone replacement therapy for classical hypogonadism. He also explains the association of low testosterone with other chronic medical conditions, including obesity, Type 2 diabetes, metabolic syndrome, and others. He opines that low blood testosterone levels are a biomarker of disease, a consequence, not a cause of these conditions. He offers the opinion that testosterone treatment cannot be recommended as a routine treatment for low blood testosterone levels associated with male aging because the reductions in blood testosterone are due to the impact of co-morbidities that frequently accompany the aging process, rather than aging itself. He notes the lack of proven efficacy in the use of testosterone therapy in aging men. He also offers opinions about the dangers of testosterone supplementation. Dr. Handelsman's report also includes opinions about the marketing of TRT products generally and Testim in particular, but, as noted below, Plaintiffs Owens and Holtsclaw do not intend to elicit any of these opinions from Dr. Handelsman.

Hossein Ardehali, M.D., Ph.D.

Dr. Hossein Ardehali is a cardiologist and research physician with both an M.D. degree and a Ph.D. in molecular physiology and biophysics from Vanderbilt University. He is board-certified in cardiovascular medicine and is a Fellow of the American College of Cardiology and the American Heart Association. Ardehali Report, Ex. 3 at 2. Dr. Ardehali is currently a tenured professor of Medicine – Cardiology and Pharmacology at the School of Medicine, Northwestern University, as well as the Director of the Center for Molecular Cardiology there. *Id*. Ardehali provided general causation and specific causation opinions with respect to the AbbVie cases and his credentials – which are not challenged here –were discussed in detail in the briefing on the AbbVie Defendants' motions to exclude those opinions.

Dr. Ardehali provides a case-specific report ("Ardehali Report") with respect to the cause of Plaintiff Holtsclaw's heart attack.[3] It is Dr. Ardehali's opinion that, but for the use of the Testim testosterone product, Mr. Holtsclaw would not have experienced the thrombotic event in his coronary arterial system on July 3, 2014, which caused his MI and myocardial damage and that the Testim therapy was a substantial factor in causing the heart attack. *See* Ardehali Holtsclaw Report, Ex. 15 at 13.

Jihad Abbas, M.D.

Dr. Abbas is a Board Certified vascular surgeon at the Jobst Vascular Institute in Toledo, Ohio and is an Associate Professor in the Department of Surgery at the University of Toledo. Abbas Report at Appendix B. He received an M.D. degree in 1992 and completed his residency in General Surgery at New York University Medical Center/Bellevue Hospital and at the Medical College of Georgia Hospital and Clinics in August, Georgia. Thereafter, he completed a fellowship in vascular surgery at Baylor College of Medicine/Methodist Hospital in Houston, Texas. Since then, Dr. Abbas served on the faculty at the University of Toledo Medical Center and the University of Toledo Jobst Vascular Institute. He is Board-certified in general surgery and vascular surgery.

Dr. Abbas provided a report with respect to Plaintiff Owens ("Abbas Report"). He offers six opinions, covering both general and specific causation in this case. With respect to general causation, he offers the opinion that "[t]he administration of exogenous testosterone can cause or increase the risk of occurrence of venous thromboembolic disease through a variety of mechanisms." Abbas Report at 4. With respect to specific causation, he opines that "[b]ut for the administration of Testim to Mr. Owens in the July 2013, he would not have developed a deep

[3] Dr. Ardehali also offers a general causation opinion, in this instance, with respect to Auxilium's TRT product Testim. Defendants do not challenge the admissibility of his general causation opinions.

venous thrombosis in his left leg. Testim was a substantial factor in causing Mr. Owens' left lower extremity clotting event." Abbas Report at 5.

Ardel Cagata, M.D.

Dr. Ardel Cagata received his medical degree from the University of Louisville, Kentucky, where he also completed a three-year residency in internal medicine. He is Board Certified in internal medicine and practices in a subspecialty of that field, hospital medicine. *See* Cagata Tr. Ex. 4 at 27:19-28:3, 24:18-25:16. As a hospitalist, Dr. Cagata treats patients exclusively in a hospital setting; he admits patients who need to be admitted to the hospital, and then takes care of them. *See* Cagata Tr. at 26:18-27:8. On July 12, 2013, Dr. Cagata admitted Isaac Owens to Norton Audubon Hospital in Louisville and was the attending provider for Mr. Owens until his discharge from the hospital the next day. Cagata Tr. at 33:2-35:18. Mr. Owens was admitted for a possible deep-vein thrombosis, a diagnosis that was confirmed by ultrasound at Norton Audubon.

Dr. Cagata provided no expert report. He was subpoenaed for deposition by the Defendants for testimony concerning his treatment of Mr. Owens. During the course of the deposition, Dr. Cagata provided factual testimony about Mr. Owens's DVT, his hospitalization, and his medical records. Dr. Cagata also offered certain opinions base on his medical training and his experience as a hospitalist treating DVTs. Both sides designated Dr. Cagata as a non-reporting expert and provided summaries of fact and opinion testimony they expect to elicit from him.

Martin Ozor, M.D.

Like Dr. Cagata, Dr. Martin Ozor is and was Isaac Owens's family doctor. Dr. Ozor received his M.D. in 2003 and then completed a residency in family medicine at the Rush Medical Center in Chicago. He is Board Certified in family medicine and practices in Louisville, Kentucky. *See* Ozor Tr., Ex. 5 at 14-15.

Dr. Ozor provided no expert report. He was subpoenaed for deposition by the Defendants for testimony concerning his care of Mr. Owens. During his deposition, he provided factual

testimony about Mr. Owens's medical conditions and medications. He also offered opinions based on his medical training. Both sides designated Dr. Ozor as a non-reporting expert and provided summaries of fact and opinion testimony they expect to elicit from him.

LEGAL STANDARDS

This Court has set forth the legal standards to be applied on a motion under Fed. R. Evid. 702 in its ruling on the AbbVie Defendants' motion to exclude the testimony of Plaintiffs' experts. *See* CMO 46, Doc. #1895 (May 8, 2017); CMO 48, Doc. #1897 (May 8, 2017).

ARGUMENT

I. THE TESTIMONY OF PLAINTIFFS' REGULATORY AND OFF-LABEL MARKETING EXPERTS SHOULD NOT BE EXCLUDED

A. The Opinions Offered by Dr. Pence Are Admissible

Defendants make only a limited challenge to the opinions of Dr. Peggy Pence, seeking to exclude what they term her "marketing" opinions. But the opinions Dr. Pence offers are regulatory, not marketing, opinions and are, in any event, admissible.

1. Dr. Pence Does Not Speculate About Auxilium's Intent

Auxilium argues that Dr. Pence's opinions include speculation about Auxilium's "intent," but the examples it provides show that Dr. Pence is not speculating about what Auxilium intended, but rather about what Auxilium *knew*. Unlike a party's subjective intent, about which an expert may lack a basis to testify, *knowledge* may be determined objectively from the documentary record. Defendants seek to exclude three specific portions of Dr. Pence's testimony on this basis, but examination of each shows that their arguments lack merit.

First, Dr. Pence's assertions that Auxilium knew that Testim was not approved to treat age-related or late-onset hypogonadism or that it knew that Testim was being prescribed for these purposes are descriptions of the record evidence establishing such knowledge. Dr. Pence describes correspondence between Auxilium and the FDA in 2001 and 2002 in which Auxilium sought an indication for what it called "secondary hypogonadism" and which it defined as "insufficient

production and secretion of testosterone *due to aging*." Pence Report at 43, *citing* AUXILIUM_MDL_REG_000074029 at 049: Auxilium Revised Proposed Labeling (10/28/2002) (emphasis added). The FDA denied the request. Auxilium then submitted a memorandum to the FDA again requesting that age-related hypogonadism and low testosterone symptomatology be included in the Testim label. Again, the FDA refused to allow references to age-related hypogonadism or low testosterone symptomology. Thus, as Dr. Pence explains, "Auxilium was informed that the Testim product is not indicated for the treatment of aging or age-related hypogonadism." Pence Report at 43.

Auxilium's knowledge on this point was confirmed at the deposition of its own Senior Director of Regulatory Affairs. She was asked: "[W]as Testim approved by the FDA to treat age-related hypogonadism?" She answered: "I don't believe so." Pence Report at 60-61, *citing* Deposition of Laura Grablutz, December 15, 2016, 388:19 – 389:3, 392:4-21. In a 2013 document distributed to Auxilium leadership, the same Senior Director of Regulatory Affairs put it more emphatically, stating "We do not have an indication for age-related hypogonadism." Pence Report at 61, *citing* AUXILIUM_MDL_CUST_000759083 at 084 and AUXILIUM_MDL_CUST_000267961 at 962. Dr. Pence's statement that Auxilium *knew* that Testim had not been approved to treat age-related hypogonadism is not speculation about Auxilium's intentions or state of mind – it is a conclusion well-supported by the factual record.

The same is true about her assertion that Auxilium knew that Testim was nonetheless being prescribed for age-related hypogonadism. As Dr. Pence explains in her Report:

> The 2002 Testim Sales Guide recognized that the testosterone replacement therapy market was driven by "sexual problems and baby boomers' anxiety about aging":
>
> > Over the past five years, driven by more open discussion about sexual problems and baby boomers' anxiety about aging, testosterone use has almost doubled – to 1.5 million prescriptions last year. As a result, the androgen market - the market for TRT - is the fifth fastest growing market of all categories of pharmaceuticals. However, the market is still in its

> infancy, and as a result is underdeveloped. Although AndroGel® currently has 57% of the TRT market, only 2% of the available patient population is being treated. Therefore, both physicians and the patients must be educated so that they see the benefits of TRT. *The aging male must be encouraged to see his urologist for routine prostate health management and for evaluation of symptoms of low testosterone.*

Pence Report at 64-65, *citing* AUXILIUM_MDL_NCD_000137127: 2002 Testim Sales Guide (emphasis added). Dr. Pence also references the 2006 Testim Sales Guide, which noted that "Interest in treating androgen deficiency of aging men is likely to grow even more." Pence Report at 76, *citing* AUXILIUM_MDL_CUST_000727585 at 598: 2006, Testim 1% Sales Training Program. Once again, Dr. Pence's assertion about what Auxilium knew is not speculation about intent or state of mind – it is, rather, a well-supported inference of what Auxilium knew based on statements by Auxilium itself *reflecting that very knowledge*.[4]

Auxilium argues that, to the extent this is so, the jury can draw these inferences for itself, without need for expert assistance. But Dr. Pence's regulatory opinions require context that she can and should provide. Her opinion that Testim was misbranded arises in part from her review and understanding of the factual material relating to the absence of an indication for age-related hypogonadism. Her opinions about what Auxilium ought to have done – based on the regulatory framework and on industry standards – are grounded in the record showing that Auxilium knew that Testim was being widely prescribed for a use that Auxilium knew was off-label. Auxilium's obligations with respect to the labelling of its product are not unrelated to its knowledge of which

[4] Moreover, although an expert may not testify or opine that the defendant actually possessed a particular mental state, such as intent, he may testify in general terms about facts or circumstances from which a jury might infer that the defendant had a particular mental state, including intent. This is done routinely in narcotics cases. *See, e.g., United States v. Winbush*, 580 F.3d 503, 512 (7th Cir. 2009); *United States v. Lipscomb*, 14 F.3d 1236 (7th Cir.1994). In such cases "experienced narcotics investigators applied the knowledge gained through years of experience and, essentially, described for the jury what they knew about narcotics dealers." *United States v. Conn*, 297 F.3d 548 (7th Cir. 2002). Thus, even testimony pertaining to intent may be proper.

uses were off-label and of the extent to which the product was nonetheless being prescribed for such uses. Defendants' suggestion that Dr. Pence must offer her opinions without reference to the factual basis underpinning them is unsupported by any legal authority and should be rejected. Indeed, this Court has already done so, holding that another of Plaintiffs' experts, Dr. David Kessler, could provide background summaries of the voluminous records on which he based his opinions, explaining:

> Dr. Kessler's testimony will assist the jury in determining its ultimate conclusions, and it presents no danger of invading the jury's province. Moreover, to the extent he is summarizing voluminous records and materials, as appears to be the case, this aspect of his testimony is properly admitted under Federal Rule of Evidence 1006 as well as Rule 702 in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials.

CMO 48 at 33, *citing In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, No. 3:09-MD-02100-DRH, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011). The same is true here.

Second, Defendants seek to exclude testimony about concerns expressed by Auxilium's co-promoter, GlaxoSmithKline LLC. Again, Auxilium's argument is that the jury can draw its own conclusions from the underlying documents on which Dr. Pence based her opinions, but, again, Dr. Pence's summary of the voluminous record will assist the jury and explain the basis of her opinions. Auxilium's contention that Dr. Pence did not consider all of the evidence it believes to be relevant in forming her opinion is not a basis to preclude her from testifying about the facts she did consider; it is, rather, a proper subject for cross-examination. *See Walker v. Soo Line R. Co.*, 208 F.3d 581, 587 (7th Cir. 2000) (testimony of expert should have been admitted despite contention that it was based in part on inaccurate information; any in accuracies in the information on which it was based could have been explored on cross-examination.)

Third, Auxilium seeks to exclude Dr. Pence's testimony that Testim was misbranded in light of the drug's intended use. Auxilium objects both to testimony about "misbranding" and about "intended use." It claims that "intended use" calls for improper speculation or narrative about the company's intent, but this Court has already found that testimony about the "intended use" of a TRT product is "properly admissible." CMO 48 at 33-34. As the Court recognized, such testimony "evaluates [Defendant's] marketing materials and internal memoranda to assess whether and to what extent it was targeting persons with conditions outside of [the TRT products'] indicated use." It also "offers a framework by which the jury can assess what [the Defendant] intended via its marketing." *Id.* at 34. The same is true here. And, although the Court cautioned that a regulatory expert "may walk up to this line, he may not cross it; he cannot offer an opinion or conclusion about what [Defendant] intended," *id.*, Dr. Pence's Report clearly shows that her testimony falls on the right side of the line and that she has no intention of testifying about what Auxilium "intended."

Auxilium's objection to the term "misbranded" under FDA regulations is similarly unfounded. Auxilium argues that such testimony is improper because Plaintiffs' claims arise under state law, not under federal law. This Court has already found such testimony to be proper. *See* CMO 48 at 32. Moreover, as the Court noted in rejecting Defendant's preemption argument, Plaintiffs' reliance on federal regulations concerning misbranding are appropriate "in the context of establishing the standard of care that they contend [Defendant] breached, and to help establish [Defendant's] intent and motive in connection with its marketing of [its TRT product]." CMO 48 at 16. *See also id.* at 14 (noting that even though plaintiffs may not assert claims to enforce the FDCA, they may introduce evidence about the indications for which the FDA approved the product in question), *citing Eidson v. Medtronic, Inc.*, 981 F. Supp. 2d 868, 880-81 (N.D. Cal. 2013). Even though Plaintiffs are not suing to enforce the FDCA, Auxilium's violation of federal regulations

and its misbranding are relevant to the question whether state-law standards of conduct were violated. As a regulatory expert, Dr. Pence can provide proper expert testimony on the federal regulatory framework.

Finally, even if this portion of Dr. Pence's testimony may not assist the jury in understanding any "technical or scientific information," that is entirely beside the point. As the Supreme Court recognized in *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), Rule 702 applies to "scientific, technical, *or other specialized knowledge*. . . ." 526 U.S. at 141 (emphasis added); Fed. R. Evid. 702. Dr. Pence's testimony about the regulatory framework applicable to the labelling of prescription drugs surely provides "specialized knowledge" that will assist the jury, regardless of whether it is "technical or scientific."

2. Dr. Pence's Opinions Are Relevant

Defendants contend that Dr. Pence's opinions about their marketing materials are irrelevant because, they say, Plaintiffs and their prescribing physicians did not see or rely on those materials. This is wrong for two reasons. First, Defendants' violation of FDA regulations in the labelling and marketing of Testim is relevant to their knowledge and intent as well as to the standard of care in the industry and Auxilium's obligations to provide accurate information about the risks and benefits of Testim. It is relevant to whether Plaintiffs' doctors were provided adequate information from which they could properly assess the risks and benefits of Testim. Whether Plaintiffs can prove each and every element of their claims is beyond the scope of this motion, but Dr. Pence's opinions are relevant on several points besides the reliance that Plaintiffs must show to prevail on their fraud claims.

Second, Defendants are wrong that there is no evidence that plaintiffs or their doctors saw or relied on the "Low-T" disease awareness campaign or other marketing of TRT products, including Testim, for treatment of age-related declines in testosterone levels. As Plaintiffs have shown at length, there is no evidence whatsoever that TRT products provide any benefit in men

with age-related declines in testosterone and the FDA never approved any TRT products for that use. Yet Dr. Dennis Smith, Plaintiff Owens's prescribing physician echoed to a "T" the message of the disease-awareness campaign: he believed that lack of libido, decreased energy, fatigue, and muscle loss, all of which are symptoms of aging, are symptoms of "hypogonadism." *See* Smith Tr., Ex. 6 at 13:1-9. He believed that men with these symptoms, TRT products provide a "treatment option." *Id.* at 14:3-7. Dr. Marion Dean McLaughlin, Plaintiff Holtsclaw's prescribing physician, similarly believed that TRT products were appropriate treatment options for fatigue, weight change, loss of libido, erectile dysfunction, and irritability. *See* McLaughlin Tr., Ex. 7 at 22:7-24:23. Both doctors believed that Testim alleviates such symptoms. Smith Tr. at 15:5-12; McLaughlin Tr. at 26:3-12, 57:12-22. . Given the lack of scientific support for these beliefs – and statements from the FDA specifically emphasizing the lack of scientific support for these claims – a jury could conclude that Defendants were, at least in part, the source of these beliefs.

A true story may emanate from many places, but a particular falsehood is easily traced back to its source. Dr. Smith and Dr. McLaughlin could have learned the truth about testosterone from many sources unconnected to Auxilium, but the "Low-T" story, and its relevance to Testim, bears the signature of the Defendants and other TRT product manufacturers. This is especially true because Dr. Smith testified that he relies on "the literature" for information about testosterone, but could not recall a single source. *See* Smith Tr. 65:1-11. Dr. Smith also testified that he first learned of Testim through sales representatives, *see id.* at 53:1-3, and that he relies, in part, on information from manufacturer's sales representatives. *Id.* at 70:2-6. He believed that they had never provided him with information that was false or inaccurate, *see id.* at 53:18-21; in other words, he believed that everything they told him was true. Dr. McLaughlin similarly testified that he relies on information from sales representatives to be accurate and that, to his knowledge, Auxilium's representatives had never given him false information. McLaughlin Tr. 105:13-23,

117:24-118:4, 119:20-121:17, 123:4-124:7. Dr. Smith also recalled using the ADAM questionnaire. Smith Tr. at 73:10-18. This evidence is sufficient to show that the off-label marketing campaigns affected Plaintiffs' prescribers, even if neither Dr. Smith nor Dr. McLaughlin recalled any specific marketing information he received. Dr. Pence's opinions about that marketing are highly relevant.

3. Defendants Seek to Exclude Testimony They Elicited and Which Plaintiffs Do Not Propose to Offer

Defendants seek to exclude testimony from Dr. Pence about the FDA's motives and intentions. Dr. Pence has explicitly stated that she does not intend to provide such testimony. *See* Pence Tr., Ex. 8 at 155:21-23. Moreover, Dr. Pence's Report *does not contain the statements the Court found to constitute an opinion about the FDA's reasons for acting or not acting in her previous report*. This omission shows that Dr. Pence does not intend to offer this opinion. Nonetheless, at her deposition, Auxilium questioned her about her views as to why the FDA acted as it did, questions that called for her personal opinions beyond the scope of the opinions set forth in her Report. Tr., Ex. 8 at 155:16-19. It would have been improper for Dr. Pence to refuse to answer these questions, but she quite properly provided truthful answers about her views. Nevertheless, the scope of the opinions Dr. Pence intends to offer at trial is determined by her Report, not by the questions Defendants chose to ask at her deposition. Defendants may not elicit testimony for the sole purpose of seeking to exclude it and then claim that Dr. Pence is attempting to offer opinions already excluded by the Court. Nothing in Dr. Pence's report refers to the reasons for the FDA acting or not acting and no such opinion is at issue here. It is no more necessary or proper for this Court to exclude the statements at Dr. Pence's deposition about which Defendants complain than it is for the Court to preclude Dr. Pence from offering opinions on any of the infinite number of other topics *not* disclosed in her Report and not otherwise proffered by the Plaintiffs.

B. **Dr. Woloshin's Opinions Are Admissible**

Auxilium offers three arguments why the opinions of Dr. Woloshin should be excluded. First, Auxilium argues that Dr. Woloshin's testimony is irrelevant because, they say, there is no evidence that Plaintiffs or their doctors saw or relied on their advertising. This argument should be rejected for the reasons discussed above in connection with Dr. Pence.

Second, Auxilium contends that Dr. Woloshin should be precluded from offering opinions about what the "pharmaceutical industry did," including the "disease-awareness" strategies of other pharmaceutical manufacturers. It argues that it cannot be held liable for the marketing campaigns of other manufacturers. But Dr. Woloshin explains how Auxilium deliberately positioned itself to take advantage of AbbVie's unbranded disease-awareness campaign. He discusses an internal Auxilium email, sent by the Testim Marketing Team to the Testim sales representatives (referred to as "Team Testim"), explaining how AbbVie's unbranded, direct-to-consumer television campaign, "Is It Low-T?" "provides us with the opportunity to be the solution as patients are driven into their doctors office with questions about this condition." *See* Woloshin Report at ¶ 45, *citing* AUXILIUM_MDL_CUST_000685680. The email concluded: "no new competition + increased noise in the market + more patients being drive into the office = OPPORTUNITY FOR TESTIM and reaching $200M!!!" *Id.* Clearly, Auxilium's marketing strategy was to focus on the "opportunity" by marketing Testim as the "solution" when patients asked their doctors about low testosterone. Auxilium chose not to have its sale representatives remind doctors that Testim was only approved for classic hypogonadism and that age-related declines in testosterone were not an indication for the use of exogenous testosterone. Instead, Auxilium sent its sales representatives to cash in on the campaign promoting the use of testosterone generally for these off-label uses. Auxilium may not have run the disease-awareness campaign itself, but it sent its sales representatives to doctors' offices specifically to focus on this campaign and use it to direct prescribers to Testim. Because Auxilium chose to make use of this campaign

and aligned its marketing strategy reap the benefits of it, Dr. Woloshin's opinions about the campaign are highly relevant to Auxilium's knowledge and intentions, and to its liability in these cases.

Finally, Auxilium seeks to exclude Dr. Woloshin's use of certain terminology, including the phrase "disease-mongering." This Court has already excluded the use of that term and certain other language. CMO 48 at 36-41. To the extent that Defendants seek broader exclusion than the limitations set forth in CMO 48, including exclusion of the underlying opinions of Dr. Woloshin concerning marketing and promotion (rather than the language in which those opinions are couched that the Court has already excluded), that request should be denied to the same extent, and for the same reasons, that the motion to exclude the testimony of Dr. Woloshin was denied in CMO 48. With respect to the portions of his opinion excluded under CMO 48, including the use of terminology identified and excluded by the Court, Plaintiffs respectfully disagree with the Court's ruling, but agree that, under that ruling, the same language is excluded here.

C. Plaintiffs Will Not Offer Marketing or Over-Promotion Opinions from Dr. Handelsman

Defendants seek to exclude or limit the marketing and over-promotion opinions of Dr. Handelsman. Neither Plaintiff Holtsclaw not Plaintiff Owens intends to offer any opinions from Dr. Handelsman pertaining to marketing, advertising, or over-promotion, so there is no need for the Court to address this portion of Defendants' argument. Defendants raise no objection to Dr. Handelsman's opinions concerning endocrinology, hypogonadism, and the diseases listed on the Testim label, the subjects on which Plaintiffs do intend to offer his testimony.

II. DR. ARDEHALI'S SPECIFIC CAUSATION OPINION IS ADMISSIBLE

Auxilium asks the Court to exclude the testimony of Plaintiff Holtsclaw's specific causation expert, Dr. Hossein Ardehali, on the grounds that his testimony is unreliable. This

argument should be rejected because Dr. Ardehali's opinion is grounded in a reliable and well-accepted methodology, differential etiology, which he properly performed.

Differential etiology is an accepted method for establishing specific causation. *Myers v. Illinois Cent. R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010). In "a differential etiology, the doctor rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment." *Id.* As the Seventh Circuit has held, there "is nothing controversial about that methodology." *Id.* A differential etiology "satisfies a *Daubert* analysis if the expert uses reliable methods." *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 772 (7th Cir. 2014). This Court has already held that a properly-conducted differential etiology "is a reliable methodology for making a specific-causation determination." *See* CMO 46 at 42.

The standard for proper differential etiology under *Daubert* does not require an expert to rule out every alternative cause. *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 434 (7th Cir. 2013). The court "may consider whether they adequately account for obvious alternative explanations." *Id.*, quoting Fed. R. Evid. 702 Committee Note (2000) (internal quotations omitted). *See also, e.g., Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 265 (4th Cir. 1999) (a "medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness."). "[O]nly 'where a defendant points to a plausible alternative cause and the doctor offers no explanation for why he or she has concluded that was not the sole cause'" is that doctor's methodology unreliable. *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999). The expert "must provide a reasonable explanation as to why he or she has concluded that [any alternative cause suggested by the defense] was not the sole cause of the plaintiff's injury." *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1253 (11th Cir. 2010) (internal quotations omitted).

Dr. Hossein Ardehali offers the case-specific opinion that

> But for the use of the Testim testosterone product, Mr. Holtsclaw would not have experienced the thrombotic event in his coronary arterial system on July 3, 2014, which caused his MI and myocardial damage. The Testim therapy was a substantial factor in causing this acute clotting event because of its effects on coagulation under circumstances of a systemic chronic inflammatory disease.

Ardehali Report at 12. Defendants seek to exclude this opinion, arguing that it lacks a reasonable basis, but their arguments lack merit.

As Defendants recognize, under Tennessee law, Mr. Holtsclaw need not prove that Testim was the only cause of his heart attack. In Tennessee, a plaintiff must demonstrate only "that the alleged conduct of the defendants [was] a *substantial factor* in causing the injury complained about[.]" *Naifeh v. Valley Forge Life Ins. Co.*, 204 S.W.3d 758, 771 (Tenn. 2006) (emphasis added). Nor does *Daubert* require Dr. Ardehali to rule out completely every alternative cause. *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 434 (7th Cir. 2013).

In reaching the conclusion that Testim was a "substantial factor" in causing Mr. Holtsclaw's heart attack, Dr. Ardehali used a differential etiology. His report on Mr. Holtsclaw follows precisely the same methodology as that reflected in his report concerning Jesse Mitchell, a method that Dr. Ardehali himself described as a "differential diagnosis," a "list of diagnosis that could explain the patient's medical problem." *See* Ardehali/Mitchell Dep. Tr., Ex. 9 at 311:10-312:16. This Court has previously recognized that "a differential diagnosis, also referred to more accurately in this context as a 'differential etiology,' is a reliable methodology for making a specific-causation determination." CMO 46 at 42, *citing Schultz*, 721 F.3d at 433 (differential diagnosis and differential etiology are "generally accepted means for evaluating the cause of a plaintiff's injury"). Here, Dr. Ardehali relied on his own general causation report (the admissibility of which Defendants do not challenge) to "rule in" Testim as a possible cause of Mr. Holtsclaw's heart attack. He then considered each of Mr. Holtsclaw's other risk factors and determined that

they "increase[d] the atherosclerotic burden and associated chronic inflammatory state on which testosterone acts to cause an acute coronary artery thrombotic event." Holtsclaw Rep. at 12. On that basis, he concluded both that "[t]he Testim therapy was a substantial factor" in causing Mr. Holtsclaw's heart attack and also that "[b]ut for the use of the Testim testosterone product, Mr. Holtsclaw would not have experienced the thrombotic event in his coronary arterial system on July 3, 2014. . . " *Id.*

Auxilium compares Dr. Ardehali's report to that of Dr. John Setaro, based on which this Court excluded the opinions of Dr. Setaro in its previous ruling. *See* CMO 46 at 54-56. This argument is easily disposed of by comparison of Dr. Ardehali's report to both Dr. Setaro's report, on the one hand, and Dr. Ardehali's own prior report with respect to Jesse Mitchell, which this Court previously found to be admissible, on the other. Such comparison shows that Dr. Ardehali's methodology in forming his opinions about Mr. Holtsclaw was not at all similar to the methodology used by Dr. Setaro but rather was nearly identical to the methodology used by Ardehali in the Mitchell case-specific report. As this Court previously explained, "apart from this discussion of the mechanism by which AndroGel might contribute to increased cardiovascular risk, Dr. Setaro does not point to anything about [the plaintiff's] case in particular to suggest that his injury was the result of AndroGel rather than the multiple other risk factors that Dr. Setaro was unable to rule out." CMO 46 at 55. By contrast, this Court described Dr. Ardehali's opinion:

> Though Dr. Ardehali did not rule these risk factors out as potential causes of Mitchell's heart attack, he does explain in his report why he believes they did not constitute the sole cause of the particular myocardial infarction Mitchell suffered. Dr. Ardehali acknowledges that risk factors other than AndroGel were integral in the formation of the lesions that were found on Mitchell's artery. But Dr. Ardehali explains why, under his theory of the mechanism by which TRT causes cardiovascular injuries, AndroGel played a significant role in causing the "acute thrombotic event" that led to Mitchell's ultimate injury. According to Dr. Ardehali, it is the pro-thrombotic effects of TRT that can provoke such events in patients like Mitchell who have already developed atherosclerosis as a result of longstanding risk factors.

CMO 46 at 49.

As was true with AndroGel and Mr. Mitchell, Dr. Ardehali's report concerning Mr. Holtsclaw explains why Testim played a significant role in causing Mr. Holtsclaw's "acute clotting event because of its effects on coagulation under circumstances of a systemic chronic inflammatory disease." Ardehali Holtsclaw Report at 12. Rather than ignoring Mr. Holtsclaw's other risk factors, as this Court believed Dr. Setaro had done, Dr. Ardehali specifically accounts for Mr. Holtsclaw's various risk factors worked together with the pro-thrombotic effects of testosterone to cause Mr. Holtsclaw's heart attack.

Defendants also claim that Dr. Ardehali's opinion is unreliable because Dr. Ardehali conceded at his deposition that there is no diagnostic test that establishes when testosterone was a substantial factor in causing a heart attack and that CT results for MI patients have no tell-tale marker to show when testosterone was involved. This argument should be rejected: it is simply not the case that a differential etiology must be based on that kind of direct evidence. Indeed, if there *were* a biomarker for TRT-induced heart attacks, no differential etiology would be needed at all, as it would be unnecessary to "rule in" and then "rule out" potential causes if a single diagnostic test could resolve the issue. The same is true for every case where a differential etiology is used; the differential etiology method exists precisely *because* most causes do not leave behind a signature or biomarker to make clear the causal relationship. It is for this reason that experts such as Dr. Ardehali must rely on their judgment in assessing the likely causes of an event or disease. The widespread use of differential etiology, and the wealth of legal authority accepting this method, refutes Auxilium's argument that there can be no proper analysis of causation in the absence of "direct" biological evidence. Moreover, even when tests do exist, but are not routinely performed (for example, measurements of thromboxane A2 and estradiol in the blood), an expert is not precluded from an offering an opinion merely because some information is missing. Rather,

expert is permitted to extrapolate from the available data. *See C.W. v. Textron, Inc.*, 807 F.3d 827, 833 (7th Cir. 2015) (experts can extrapolate from available data when data is not available that addresses the impact of an agent in the precise population at issue).

Nor are Defendants correct that Dr. Ardehali's testimony shows that he believes that Testim is the cause of every heart attack in any patient who has taken it. Rather, the testimony shows Dr. Ardehali believes that determinations must be made on a case-by-case basis, in light of the medical history of each particular patient. Dr. Ardehali was asked by Auxilium "[w]hat, if anything, was different or distinguished Mr. Holtsclaw's cardiac catheterization from a cardiac catheterization of a person with the same risk factors who did not use testosterone but presented with a STEMI [ST-elevated myocardial infarction]?" Tr. 154:11-15. He responded: "I have other information, I have the history of the patient, and I know what he has been taking. I know his risk factors and based on that information, I look at his cath films, I see features on his cath film that I can tell if he had not taken his testosterone, he would not have had the heart attack at that time." *Id.* at 155:4-11. Dr. Ardehali also noted an increase in Mr. Holtsclaw's hematocrit levels while he was using Testim. *Id.* at 159:2-160:6. Thus, Dr. Ardehali insisted that individual factors are required for the specific-causation analysis in his report. Indeed, presented with the "twin brother" hypothetical Defendants discuss in their brief, Dr. Ardehali rejected the premise of the question, explaining:

> I think the problem here is that you are, you know, you are looking at a complex process and you are trying to make that simplified in terms of one person versus the twin brother. *No two people are exactly the same*, and that's I think what you're trying to do here, to say there is one person and there is a twin brother and they both had a heart attack and one was on Testim, the other one wasn't.

Id. at 138:2-10 (emphasis added). He reiterated: "You are trying to simplify the complex human body and the complex process of a heart attack by comparing a brother to his twin brother. And

that is not – that's not a good comparison." *Id.* at 139:10-13.[5] Moreover, when he was specifically asked if he would assign Testim as the cause for every heart attack in any patient taking Testim, he responded:

> No. What I'm saying is that if there is a patient who has the substrate, has the background of having higher risk of a heart attack, and they are put on Testim -- I'm sorry -- they are put on Testim and they have a heart attack within a few months and then you do a cath and you find a clot I would say Testim caused it.

Id. at 139:19-140:1.

In this context, it is significant that Dr. Ardehali does not opine – nor, under Tennessee law, need he – that Mr. Holtsclaw would never at any time have had a heart attack if he had not taken Testim. As Dr. Ardehali recognizes, Mr. Holtsclaw had other risk factors for MI, and it is impossible to speculate whether those risk factors alone would have caused Mr. Holtsclaw to have a *different* heart attack at some *other* time in the future. Dr. Ardehali offers the opinion that "[b]ut for the use of the Testim testosterone product, Mr. Holtsclaw would not have experienced the thrombotic event in his coronary arterial system on July 3, 2014, which caused his MI and myocardial damage." Report at 12. Thus, Dr. Ardehali's opinion is that Testim was a substantial factor in causing the heart attack that Mr. Holtsclaw actually had when he had it. That is the heart attack Defendants must answer for; whether Mr. Holtsclaw might have suffered a different heart attack at a different time, even in the absence of Testim, is irrelevant to the actual injury that Defendants caused.

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[5] Indeed, Auxilium's "twin" hypothetical, as posed to Dr. Ardehali at his deposition, actually assumes that Testim did not cause Mr. Holtsclaw's heart attack. By assuming that an identical "twin" who did not use Testim (by which Auxilium appears to mean something more like a science-fiction replicant, who would share not only the same genetic makeup, but the *exact same medical history* in every detail – an assumption that is, as Dr. Ardehali stated, an impossibility in the real world) would have had the same clot and the same MI at the exact same moment, Auxilium is assuming away any causal role for Testim. That Dr. Ardehali could not describe how you could tell that Testim caused a heart attack in a scenario whose assumptions leave no causal role for Testim does not reflect any lack of reliability in the basis of his opinion that Testim was a substantial factor in causing Mr. Holtsclaw's actual heart attack.

Auxilium wrongly compares this case to *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245 (11th Cir. 2010). While *Guinn* correctly states the law, the facts of that case are entirely distinguishable. In *Guinn*, plaintiff's expert, who opined that defendant's product caused plaintiff's diabetes, was unaware, at the time she formed her opinion, of much of the plaintiff's medical history, including her weight fluctuations, her "sedentary lifestyle, a poor diet, a significant family history of diabetes, hypertension, hyperlipidemia, schizophrenia, and prediabetes." 602 F.3d at 1249. The expert in *Guinn* failed even to consider these factors, since she did not even know about them. Moreover, and most significantly here

> When asked what she had done to rule out Guinn's other risk factors as the sole cause of Guinn's diabetes, Dr. Marks stated *she knew of no methodology for ruling out alternative causes and thus had not attempted to do so*. In fact, Dr. Marks agreed Guinn's other risk factors alone were sufficient to explain the onset of her diabetes. Dr. Marks stated, however, she had "no way of ruling out the Seroquel any more than she could rule out any other risk factors."

Id. at 1249-50 (emphasis added). Indeed, the expert in *Guinn* admitted that "she could not rule out the possibility that Guinn had diabetes before ever taking Seroquel." *Id.* at 1250. Here, by contrast, Dr. Ardehali was fully aware of, and considered, all of Mr. Holtsclaw's medical history. *See* Report at 3; 12**.** Far from claiming he could not rule out other factors as the sole causes of Mr. Holtsclaw's heart attack, Dr. Ardehali specifically found that the other risk factors, separately or in combination, were insufficient and that "[b]ut for the use of the Testim testosterone product, Mr. Holtsclaw would not have experienced the thrombotic event in his coronary arterial system on July 3, 2014, which caused his Ml and myocardial damage." *Id.* at 12. While the expert in *Guinn* may have lacked a reliable foundation for her opinion, that same cannot be said of Dr. Ardehali in this case.

III. DR. ABBAS'S CAUSATION OPINIONS ARE ADMISSIBLE

Auxilium makes three arguments why the specific causation testimony of Dr. Abbas, the case-specific expert on general and specific causation for Plaintiff Owens, should be excluded.[6]

A. Dr. Abbas' Opinion Relies on Solid Scientific Principles, Not Mere Temporality

First, Defendants argue Dr. Abbas's opinion that Testim "was a substantial factor in causing Mr. Owens' left lower extremity clotting event" is based on nothing more than general causation – that Testim can cause such events – plus the temporal sequence. But this is not so. As Dr. Abbas explained at his deposition, his conclusion was based in substantial part on "Virchow's Triad," three factors that contribute to thrombosis: hypercoagulability, endothelial injury, and stasis. *See* Abbas Tr., Ex. 10 at 88:14-91:15, 106:6-22, 108:20-109:7, 119:4-121:6, 198:5-12, 222:3-18. As Dr. Abbas explained, Mr. Owens's prior DVT resulted in endothelial injury and his stroke reduced his mobility, resulting in stasis. *Id.* at 89:4-8. Thus, according to Dr. Abbas, Mr. Owens already had two of three causal factors for DVT under Virchow's Triad. *Id.* at 91:8-15, 106:6-22. He had had these two factors for years without incident, and then something changed: he began using Testim. As Dr. Abbas explained, testosterone, both by its effect on platelets and by its aromatization into estradiol, causes hypercoagulability. *Id.* at 88:4-22, 91:8-15. This added the third factor of Virchow's Triad, thus completing the cycle. *Id.* at 91:11-15. This is not mere temporality – it is a reasoned analysis, grounded in the well-established science of Virchow's Triad. That Defendants have arguments that could support a different conclusion does not provide a basis to exclude Dr. Abbas's opinion.

Defendants mischaracterize Dr. Abbas's opinion as relying on temporality, when it does not. Nevertheless, temporality is an appropriate factor to consider. "[D]epending on the circumstances, a temporal relationship between exposure to a substance and the onset of a disease

[6] Although Dr. Abbas also offers general causation opinions, Defendants do not seek to preclude them. All of their argument are addressed to Dr. Abbas's specific causation opinions.

or a worsening of symptoms can provide *compelling evidence of causation*." *Westberry*, 178 F.3d at 265 (emphasis added) (finding that a doctor's testimony based on differential diagnosis and the temporal connection to exposure to talc sufficient to establish specific causation). The same is true here, but it does not mean that Dr. Abbas failed to consider other factors and other possible causes. Indeed, the Seventh Circuit has made clear that, even where an expert's causation opinion is based entirely on a temporal sequence, the opinion may be admissible. In *Cooper v. Carl A. Nelson & Co.*, 211 F.3d 1008, 1020 (7th Cir. 2000), *as amended on denial of reh'g and reh'g en banc* (June 1, 2000), plaintiff's expert "essentially testified that a patient history indicating freedom from pain before a given event followed by pain of the type experienced and observed following the incident was a sufficient basis for diagnosis and treatment of Mr. Cooper's chronic pain syndrome." The Seventh Circuit found this testimony admissible:

> The possibility of Mr. Cooper's CPS being attributable to a factor other than the fall is a subject quite susceptible to exploration on cross-examination by opposing counsel. Similarly, the accuracy and truthfulness of the underlying medical history is subject to meaningful exploration on cross-examination and ultimately to jury evaluation. Therefore, Nelson's contention that other conditions of Mr. Cooper's might have caused his CPS goes to the weight of the medical testimony, not its admissibility. Notably, on cross-examination of Dr. Richardson, Nelson elicited testimony that Dr. Richardson had really done no investigation into the causes of Mr. Cooper's CPS; Nelson presented evidence that Mr. Cooper suffered physical maladies before July 7, 1992; it also presented evidence that Mr. Cooper had been less than truthful in the history he submitted to Dr. Richardson. This evidence would permit a jury to conclude that the fall did nothing to cause CPS. The proper method of attacking evidence that is admissible but subject to doubt is to cross-examine vigorously, to present contrary evidence, and to give careful instructions on the burden of proof. *Daubert* acknowledged the continuing vital role that vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof" . . . are to play in the trier of fact's ultimate evaluation of admissible but shaky evidence.

Id. at 1021 (citation omitted). Here, as in *Cooper*, the proper method of attacking Dr. Abbas's evidence is cross-examination, the presentation of contrary evidence, and proper jury instructions. *See Daubert*, 509 U.S. at 596.

B. Dr. Abbas Missed No "Critical Facts" in Arriving at His Opinion and He Need Not Accept Defendants' Version of the Facts

Defendants also argue that Dr. Abbas failed to consider certain aspects of Mr. Owens's medical history. To the contrary, Dr. Abbas considered the entirety of Mr. Owens' medical history, and in any event, that issue is for cross-examination.

First, Defendants claim Dr. Abbas did not review the deposition testimony of Mr. Owens' primary care physician, but that contention is simply inaccurate. Dr. Abbas *did* review and rely on the deposition testimony of Dr. Ozor, who is Mr. Owens' long-time PCP. *See* Abbas Report at 15. He never said otherwise in his deposition.

Second, even if Dr. Abbas did not read the deposition testimony of Mr. Owens's other doctors, he did review and rely on seventeen sets of Mr. Owens' medical records, totaling 3,794 pages, including the medical records of Drs. Smith and Thompson. (Abbas Report at 14–15.) Importantly, Dr. Thompson testified that he has no memory of Mr. Owens and agreed that his "testimony this morning was entirely based on reading the records." Thompson Tr., Ex. 11 at 71:24-72:12. And, while Dr. Smith knows and remembers Mr. Owens, he never once provided any more information during his deposition about his treatment of Mr. Owens than was in the records. *E.g.*, Smith Tr. 31:21–24; *id.* 32:1–3; *id.* 32:12–15; *id.* 44:8–11; 46:22–47:1; 50:9–12. Dr. Abbas could not have missed a single "critical fact" by not reading those two deposition transcripts.

Third, and most importantly, what Auxilium calls "critical facts" are the subject of factual dispute. It is true that Mr. Owens's testimony shows that during his initial period of use, he used too little Testim and applied it to his thighs and abdomen rather than upper arms and shoulders. *See* Owens Tr., Ex. 12 at 192:7-192:21; *id.* 198:11–198:24. (This is because Dr. Smith originally sent Mr. Owens for lab work including a testosterone level, then called a prescription for Testim into the pharmacy without seeing Mr. Owens again or educating him on the proper usage.

Dr. Smith Tr. 35:17–36:7; Owens Tr. 199:1–199:4.) In July, 2013, however, Dr. Smith found out Mr. Owens had been using the incorrect amount and attributed his continuing flagging energy to this. *See* Exhibit 13 at 0071; Smith Tr. 40:3–12; *id.* 43:5–8; 47:2–11. At the July 3, 2013 appointment, Dr. Smith wrote a new prescription and gave Mr. Owens instructions to use a full tube every day. *Id.* 0071. Mr. Owens was admitted to the hospital on July 12, 2013 and diagnosed with an extensive deep vein thrombosis. Exhibit 14.

The amount of Testim Mr. Owens used between July 3 and July 12, 2013 is a fact question for the jury. Mr. Owens indicated on his Plaintiff Fact Sheet that he used a full tube daily. *See* Def. Ex. 2. At one point during his deposition, he said he would "guess" he was still using the dime-sized amount in this time, but later said he had no memory of how much he would have used. *Compare* Owens Tr. 234:5–23 with *id.* 289:9–20. Moreover, Mr. Owens trusts Dr. Smith and follows his medical advice. *Id.* 255:1–15. Because the first Testim prescription was called into the pharmacy directly without a further conversation on how to use it, and because the first time Dr. Smith discovered Mr. Owens was using too little was July 3, 2013, and because Dr. Smith specifically then instructed Mr. Owens to use a full tube daily, the amount of Testim Mr. Owens used between July 3 and July 12, 2013 remains for the jury to decide.

In spite of this factual dispute, Defendants are asking that Dr. Abbas accept their version of the facts in rending his opinion. This has no support in the law. *See Walker,* 208 F.3d at 586-87 (where expert based opinion on information in medical records defendant claimed was inaccurate, proper remedy was cross-examination and opinion should have been admitted); *Richman v. Sheahan*, 415 F. Supp. 2d 929, 943 (N.D. Ill. 2006) ("It is not an answer to say that the underlying facts on which the experts base their opinion came from arguably biased sources.") (Cole, MJ); Defendants argument is directly addressed -- and refuted -- in the Committee Notes to Rule 702 itself:

> When facts are in dispute, experts sometimes reach different conclusions based on competing versions of the facts. The emphasis in the amendment on "sufficient facts or data" is not intended to authorize a trial court to exclude an expert's testimony on the ground that the court believes one version of the facts and not the other.

Fed. R. Evid. 702, Advisory Committee Note to 2000 Amendment.

Dr. Abbas reviewed and relied on Mr. Owens's medical records in reaching his conclusion; those records reflect that Mr. Owens was prescribed and used Testim. To the extent the there is a question about the accuracy of the records, Defendants will be entitled to offer evidence at trial concerning Mr. Owens actual use of Testim. They may explore the extent to which Mr. Owens's use of Testim as prescribed is necessary to Dr. Abbas's opinion and to what extent facts contrary to those on which Dr. Abbas relied would undercut his opinion. But Dr. Abbas was not required to act as the fact-finder and determine for himself how much Testim Mr. Owens actually used. He can offer an opinion based on Plaintiff's view of the facts, as supported by Mr. Owens's medical records. *Walker*, 208 F.3d at 586-87.

C. Dr. Abbas did not "Cherry Pick" Evidence and his Opinion Should not be Excluded for Failing to Mention Defendants' Favorite Studies.

Finally, Defendants seek to exclude Dr. Abbas's opinion on the basis that he "cherry-picked" evidence to support his conclusion. They note, for example, that he failed to discuss the Sharma, Li, or Baillargeon studies in his report. But Dr. Abbas testified that he considered the Baillargeon study in reaching his conclusion. *See* Abbas Tr. 144:2-147:19; *see also* Abbas Report at 12 (listing the Baillargeon study as material he considered). As Dr. Abbas testified, he determined that Baillargeon did *not* contradict his view because it was not applicable to the facts of Mr. Owens's case. *Id.* He further testified that he considered other studies that, like Baillargeon, showed no increased risk in VTE as a result of TRT use, and rejected them for similar reasons. *See id.* at 147:10-148:1. Even though Dr. Abbas did not discuss the Sharma and Li studies in his Report, he discussed them at length in his deposition, and explained why they did not belong in

his report.[7] For example, he explained that the Sharma study was unhelpful and "did not apply to Mr. Owens' case" because "the people that they used in this did not have high risk factors." Abbas Tr. 207:9–22 (emphasis added); *see also* Abbas Tr. 149:3–153:18 (discussing the limitations of Li.)

Importantly, Dr. Abbas testified that he reviewed the scientific literature specifically to find anything that would *disprove* his point. *Id.* at 147:23-148:1. Thus, Dr. Abbas's testimony shows that he did not look only at studies that would support his hypothesis; he considered the medical and scientific literature more broadly to see what supported his hypothesis, what contradicted it, and which of the studies he found best matched the facts of the case before him.[8]

Dr. Abbas provided reasoned explanations for why particular studies that he discounted were not applicable. This was sufficient to support his opinion. *See Knight v. Kirby Inland Marine Inc.*, 482 F.3d 347, 354 (5th Cir. 2007) (experts are not required to support their opinions with studies that "unequivocally support their conclusions"); *United States v. Bonds*, 12 F.3d 540, 561 (6th Cir. 1993) ("[a]bsolute certainty of result or unanimity of scientific opinion is not required for admissibility."); *In re Vioxx Prods. Liab. Litig.*, 401 F. Supp. 2d 565, 599 (E.D. La. 2005) (where parties viewed the available studies differently, expert testimony from both sides was admissible); *Beck v. Koppers, Inc.*, No. 03-cv-60, 2006 WL 270260, *5 (N.D. Miss. Feb. 2, 2006) (failure of expert to specify weight accorded to various studies did not render ultimate judgment about the overall weight of the scientific evidence inadmissible).

[7] In fact, Dr. Abbas brought the Sharma paper to the deposition and provided it to Auxilium's counsel in response to their subpoena asking for material he had reviewed after the report. Abbas Tr. 45:4–17.

[8] Dr. Abbas is a vascular surgeon with a full caseload, not a professional expert. That this inexperienced expert – he had never been retained as an expert witness before, *see* Abbas Tr. 7:20-9:4 – did not realize he should discuss in his report the literature that he considered, analyzed, and determined was inapplicable does not mean that the methodology he used in forming his opinion was unreliable.

IV. THE OPINIONS OF THE TREATER-EXPERTS ARE ADMISSIBLE

Plaintiffs designated two of Mr. Owens's treaters, Dr. Ardel Cagata and Dr. Martin Ozor, to provide both factual and opinion testimony. *See* Plaintiffs' Disclosure of Expert Testimony Pursuant to Rule 26(a)(2)(C) ("Plaintiffs' Disclosure"). Dr. Cagata was the hospitalist who treated Mr. Owens for his DVT. Most of Dr. Cagata's "Facts and Opinions" summarized in Plaintiffs' Disclosure consist of factual matters pertaining specifically to Dr. Cagata's treatment of Mr. Owens and are rooted in his day-to-practices treating DVTs. *See* Plaintiffs' Disclosure at 2-4. The opinion testimony summarized consists of the Dr. Cagata's opinions that: (1) "Mr. Owens' use of Testim was a substantial factor in causing his DVT"; and (2) "Even though he has the risk factors of obesity, prior DVT, and hemiparalysis, Testim was also a factor in the causation and would put somebody of the edge in causing a DVT." Plaintiffs' Disclosure at 4.[9]

Dr. Ozor was Mr. Owens's family practitioner, primary care doctor. As is the case for Dr. Cagata, most of Dr. Ozor's "Facts and Opinions" summarized in the Plaintiffs' Disclosure consists of factual matters pertaining specifically to Dr. Ozor's treatment of Mr. Owens. In addition, Plaintiffs' have summarized the following opinions to be offered by Dr. Ozor: (1) "Dr. Ozor's opinion as to the cause of Mr. Owens' blood clot was that it was multifactorial."; (2) [Dr. Ozor] believes that Mr. Owens' prior stroke, his weight, his immobility, and his taking Testim were all factors that contributed to the DVT."; (3) "Dr. Ozor's opinion is testosterone replacement therapy and other hormone mediation causes blood clots that can lead to pulmonary embolisms. Hormone replacement therapy generally, including testosterone, can cause blood clots and cardiovascular

[9] As summarized in Plaintiffs' Disclosure, Dr. Cagata's testimony may also include (a) "Had [Dr. Cagata] known of the Testim use at the time, he would have considered it part of the cause of [Plaintiff's] DVT that could put a patient with other risk factors 'over the edge as far as getting a DVT.'"; and (b) "Had he known of the Testim use at the time, Dr. Cagata would also have advised Mr. Owens to stop taking it." Plaintiffs' Disclosure at 4. Plaintiffs believe that this is factual, rather than opinion testimony, because it relates specifically to Dr. Cagata's treatment of Mr. Owens, but to the extent the Court believes it is subject to Fed. R. Evid. 702, this testimony is admissible for the reasons discussed in Points III-A, III-B, and III-C, below.

disease."; (4) '[A]ging is not a cause of primary or secondary hypogonadism."; (5) Mr. Owens' erectile dysfunction and diminished libido were very similar to a case study in an Auxilium Testim sales presentation; and (6) "hormone replacement therapy is known to cause blood clots and that the cause of Mr. Owens' DVT was multifactorial, which means there was a piling on of more than one likely cause, one of which could be Testim." Plaintiffs' Disclosure at 6-7. Dr. Ozor does not offer the opinion that Testim was a substantial factor in causing Mr. Owens's DVT; for that opinion, Plaintiff relies on Drs. Abbas and Cagata.

Plaintiffs thus seek to offer limited opinion testimony from these two treaters. As discussed below, all of these opinions are admissible here.

A. **Defendants Designated Both Dr. Cagata and Dr. Ozor as Experts**

Defendants argue that neither Dr. Cagata nor Dr. Ozor has the relevant expertise to offer expert opinions in this case. *But Defendants themselves have designated both of these doctors as experts on behalf of Auxilium.* On August 11, 2017, Defendants served their Disclosure of Expert Testimony. With respect to all the treaters they designated, Defendants stated that they "reserve[d] the right to call Plaintiffs' treating physicians as non-retained experts who may offer a mixture of fact and opinion testimony based on their knowledge or experience. . . ." *Id.* at 4. In their description of the specific opinions they reserved the right to elicit from Dr. Ozor, Defendants included Dr. Ozor's opinion that "the cause of Mr. Owens' blood clot is multifactorial, including from the prior stroke, his weight, and his immobility" and that "Dr. Ozor puts Testim low on his list of possible causes of Mr. Owens' DVT." *Id.* at 11. Defendants have thus designated Dr. Ozor to provide exactly the same opinion – that the causes of Mr. Owens's clot were multifactorial. Yet, inexplicably, that they seek to preclude him from offering the same opinions on behalf of the Plaintiff. Having designated Dr. Ozor as an expert on the issue of the cause of Mr. Owens's DVT, Defendants may not now argue that Dr. Ozor's opinions on that subject are unreliable and inadmissible.

Defendants similarly identified Dr. Cagata as an expert whose opinions they might elicit at trial. They seek to offer Dr. Cagata's opinion that any one of Mr. Owens's risk factors alone would be sufficient to cause a DVT. *Id.* at 13. They further seek to offer Dr. Cagata's opinion that "Mr. Owens's history of hypertension, diabetes mellitus, stroke, hypercoagulable state, obesity, hemiparesis and prior DVT were all risks factors for a future DVT"; that "a prior DVT in Mr. Owens's left leg was a risk factor for a repeat DVT in the same location"; that he "understands that decreased mobility can increase a patient's risk of developing a DVT"; and that "Mr. Owens's African-American race might be an additional risk factor for developing a DVT." *Id.* at 13-14. Finally, they seek to offer Dr. Cagata's opinion that Mr. Owens's blood was "'not exceptionally thick' at the time of his DVT." *Id.* at 14. As with Dr. Ozor, Defendants seek to exclude opinions from Dr. Cagata on the same subjects as the opinions they seek to offer themselves. Having contended that Dr. Cagata is qualified to offer these opinions, and that the opinions are reliable, Defendants ought not be permitted to exclude opinions from the same witness on the same subject.

B. **Drs. Cagata and Ozor Are Qualified to Offer Their Opinions**

Even if the Defendants had not designated Dr. Cagata and Dr. Ozor as expert witnesses on the same subjects on which Plaintiff Owens seeks to offer their testimony, their challenge to their experts should still be rejected. Both of these doctors are qualified to offer their opinions and both provide a reliable foundation in their medical training for the opinions they offer.

Defendants suggest that Dr. Cagata is not qualified to offer opinions about the cause of Mr. Owens's DVT because, they say, most doctors are more experienced in diagnosis than in etiology. But that is an entirely generic point with no reference to Dr. Cagata. In fact, Dr. Cagata specifically testified that in his medical practice, it is common for him to treat patients with DVTs and that, in such cases, he attempts to determine the cause of a DVT. *See* Cagata Tr. at 50:6, 18-20 ("Q . . . [I]n your practice, do you attempt to determine the cause of the DVT? A. Yes."). He was then asked whether, in determining the cause of a DVT, he considers specific factors; he

testified that he considers all of them. *Id.* at 50:23-51:12. He testified that he asks patients about these other factors in order to determine the cause. *Id.* at 51:13-19.

Dr. Cagata also explained why that it was important, from a treatment perspective, to identify the cause of a DVT because the length of treatment would depend on the cause. *Id.* at 51:17-52:17. Thus, Dr. Cagata testified that in his regular practice he needs to determine the cause of a DVT in order to determine how and how long to treat it. Dr. Cagata further testified that based upon his education, background, training, and experience as a hospitalist treating deep vein thrombosis, he considered himself an expert in the diagnosis, treatment, and etiology of DVT. *See id.* at 84:17-24. All of this testimony establishes that assessing the cause of DVTs is something that Dr. Cagata does professionally in the ordinary course of his work as a physician and hospitalist. He is clearly qualified to do so in this case.

Indeed, the Seventh Circuit has reminded that there is "no requirement that an expert be a specialist in a given field," *Hall v. Flannery*, 840 F.3d 922, 929 (7th Cir. 2016); *accord Gayton v. McCoy*, 593 F.3d 610, 617 (7th Cir. 2010); *see also Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion*, 345 F.3d 15, 24 (1st Cir. 2003) ("proffered expert physician need not be a specialist in a particular medical discipline to render expert testimony relating to that discipline"); *McCullock v. H.B. Fuller Co.*, 61 F.3d 1038, 1043 (2d Cir. 1995) (doctor need not be a specialist in the exact area of medicine implicated). Indeed, "courts often find that a physician in general practice is competent to testify about problems that a medical specialist typically treats." *Gayton*, 593 F.3d at 617. "The fact that an expert may not be a specialist in the field that concerns her opinion typically goes to the weight to be placed on that opinion, not its admissibility." *Hall*, 840 F.3d at 929. Dr. Cagata's medical training and his professional experience as a hospitalist have given him expertise in assessing the causes of DVTs, something he does on a regular basis in his practice. That is sufficient qualification here.

Defendants make a slightly different argument with respect to Dr. Ozor, contending that Dr. Ozor is not qualified to offer opinions that hormone therapy can cause DVTs because he does not have familiarity with Testim in particular. But Dr. Ozor does not purport to opine specifically about Testim. Most of the opinions Plaintiffs seek to offer pertain to the effects of hormones generally. As a medical doctor, Dr. Ozor is qualified to offer these opinions. As discussed above, Dr. Ozor does not need to practice in a particular area to provide medical opinions within the scope of his knowledge and expertise. As a family practitioner, Dr. Ozor encounters a variety of medical conditions; he is required to understand generally the effect of exogenous hormone treatments, even if he has no particular knowledge of Testim. The same is true with respect to Dr. Ozor's opinion that aging is not a cause of hypogonadism; he has sufficient expertise, as a family practitioner, to offer this opinion. *See Gayton*, 593 F.3d at 618 (physician expert did not need to be a cardiologist to testify that vomiting and diuretics may have contributed to tachycardia and death from heart failure because "[t]he effects of vomiting on potassium and electrolyte levels in the body is not specialized knowledge held only by cardiologists, and . . . it is knowledge that any competent physician would typically possess"). The only opinions that Dr. Ozor offers that refer specifically to Testim are that (1) Testim was a factor that contributed to Mr. Owens's DVT; and (2) Testim "could be" one of the multifactorial causes of Mr. Owens's DVT.[10] Given Dr. Ozor's knowledge of the effects of hormone treatments on clotting, he is qualified to offer the opinion that Testim could be one of many causes. As noted above, Dr. Ozor does *not* purport to opine that Testim was a substantial factor in causing Mr. Owens's DVT, so his lack of particular familiarity with that product is no impediment to the opinions he does offer.

[10] Dr. Ozor also opined that Mr. Owens's medical history was similar to a case study in some of Auxilium's marketing materials for Testim. *See* Plaintiffs' Disclosure at 6. But this was not an opinion about Testim, but rather a comparison of a case study in materials placed before him and Mr. Owens's actual medical history, a comparison that Dr. Ozor, as a family practitioner, was well-qualified to make.

C. The Opinions of Drs. Cagata and Ozor Are Reliable and Relevant

Defendants argue that Drs. Cagata and Ozor lack a reliable methodology for their opinions, but this is not so. Because these treaters did not provide expert reports, their methodologies were not spelled out in the manner typically found in a report. But each of them described his methodology at his deposition; based on this testimony this Court can readily conclude that Drs. Cagata and Ozor used reliable methodologies and that, informing their opinions, each applied "the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999).

As described above, Dr. Cagata testified about the methodology he uses in his practice to determine the cause of a patient's DVT. As he explained, he considers a patient's other conditions (co-morbidities); his medical history; prior DVTs; and medications. *See* Tr. 50:23-53:17. Based on this testimony about Dr. Cagata's ordinary practices in his field, this Court can conclude that the opinion he formed about Mr. Owens's DVT reflects the same methodology, and thus the same level of intellectual rigor, as Dr. Cagata uses in treating his patients. *See Kumho Tire*, 526 U.S. at 152.

Dr. Cagata offered this opinion "within a reasonable degree of medical probability" and he testified that the opinion was based on his "education, background, training, experience in treating DVT as a hospitalist. . ." *Id.* at 83:13-19. Although he did not use the term, the methodology Dr. Cagata described was a differential etiology, first "ruling in" the possible causes, then "ruling out" any that can be excluded to arrive at the remaining causes. As noted above, a properly-conducted differential etiology provides a sufficient basis for the admissible of expert testimony. *See Brown*, 765 F.3d at 772. Here, Dr. Cagata testified that, as he does for all DVT patients, he assembled a list of possible causes for Mr. Owens's DVT when he treated him. Cagata Tr. 50:18–51:19. Dr. Cagata also testified that, at the time he originally assembled the list of possible causes, he did not know that Mr. Owens was using Testim and thus did not know to include Testim among

the possible causes of the DVT. *Id.* at 78:17-79:3. He further testified that, had he known Mr. Owens was using Testim, he would have included the drug on his list of possible causes. *Id.* at 79:4-10. Dr. Cagata declined to include on his list certain other potential causes of DVT: smoking, alcohol use, and drug use. *Id.* at 84:3-16. Dr. Cagata thus made a reasoned judgment about which factors to "rule in" when considering the possible causes of Mr. Owens's DVT. *See Cooper v. Carl A. Nelson & Co.*, 211 F.3d 1008, 1020 (7th Cir. 2000), *as amended on denial of reh'g and reh'g en banc* (June 1, 2000) ("the methodology of physical examination and self-reported medical history. . . is generally appropriate.").

Dr. Cagata also testified that, after assembling his list of possible causes of Mr. Owens's DVT, he found that none of them, including Testim, could be ruled out as a substantial factor. *See id.* at 81:11-83:11. He specifically testified that while Mr. Owens's other risk factors could not be ruled out as substantial factors, Testim was still is a substantial factor in causing the DVT. *Id.* at 83:11. Dr. Cagata's method was thus identical to a differential etiology – he ruled in all the potential causes and then assessed whether any could be ruled out as not being a factor. The fact that he opined that Mr. Owens's DVT had multiple causes and that Testim was only one of those multiple causes does not in any way diminish the reliability of his opinion. *See Gayton*, 593 F.3d at 619 ("an expert need not testify with complete certainty about the cause of an injury; rather he may testify that one factor could have been a contributing factor to a given outcome"). Indeed, in *Gayton*, the Seventh Circuit concluded:

> [G]iven that none of the medical experts in this case can determine the exact cause of Taylor's untimely death, aside from non-specific heart failure, the jury should hear testimony, backed by accepted medical science, about factors that could have exacerbated her heart condition. After hearing from all of the experts, and after vigorous cross-examination, it will be up to the jury to determine which of these factors, if any, proximately caused an injury to Taylor.

593 F.3d at 619. Here, too, the jury should hear testimony, backed by accepted medical science, about the possible cause of Mr. Owens's DVT and, after vigorous cross-examination, decide

whether among the possible factors, Testim was a substantial factor in causing that injury.

Dr. Ozor's testimony similarly provides a sufficient, reliable basis for his opinions. As noted above, Dr. Ozor does not opine that Testim was a substantial factor in causing Plaintiff's DVT. The opinions he does offer, about the effects of hormones on clotting, are based on his medical education and training. The same is true for his opinion that aging is not a cause of primary or second hypogonadism (an assessment with which the FDA agrees). That is a sufficient basis for these opinions. *See Daubert*, 509 U.S. at 592 (requiring testimony of an expert to have "a reliable basis in the knowledge and experience of his discipline"); *Kumho Tire*, 526 U.S. at 150-151 (emphasizing flexibility of *Daubert* inquiry depending on type of expertise at issue); *see also Gayton*, 593 F.3d at 618 (recognizing that some matters are within the knowledge that any competent physician would typically possess). Moreover, although these opinions do not, by themselves, establish specific causation in this case, they do provide helpful background for the jury on the effects of testosterone. Dr. Ozor also has a reliable foundation for his opinion that Mr. Owens's medical history was similar to that of the case-study in the Auxilium sales presentation he was shown. The sales presentation presented a hypothetical medical history; Dr. Ozor used his medical training and expertise to compare the medical history in the presentation with that of Mr. Owens.

CONCLUSION

For the foregoing reasons, Defendants' motion to exclude expert testimony under Rules 702 and 403 of the Federal Rules of Evidence should be denied in its entirety.

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Respectfully submitted,

/s/ Trent B. Miracle

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CERTIFICATE OF SERVICE

I hereby certify that on October 2, 2017, I electronically transmitted the foregoing document to the Clerk of the United States District Court using the CM/ECF system for filing and service to all parties/counsel registered to received copies in this case.

/s/ Brendan A. Smith

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